

## **EXHIBIT B**

Docket No. 22956-214  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

Shelby L. Cook et al.

Application No. 10/615,625

Filed: June 27, 2003

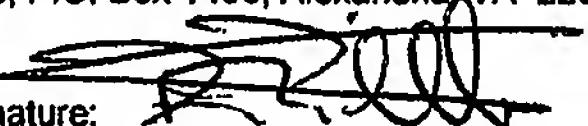
For: **BIOABSORBABLE SUTURE ANCHOR  
SYSTEM FOR USE IN SMALL JOINTS**

Confirmation No. 9377

Art Unit: 3731

Examiner: Tuan Van Nguyen

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: September 2, 2009 Signature:   
(Rory P. Pheiffer)

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard**  
**Pursuant to 37 C.F.R. § 1.131**

Dear Sir:

We, Shelby L. Cook, residing at 33 Fairway Lane, Foxboro, MA 02035, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, Karl S. Reese, residing at 764 Tremont Street, #5 Boston, MA 02118, and Thomas A. Shepard, residing at 5250 Greens Dairy Road, Raleigh, NC 27616, hereby declare as follows:

1. As co-inventors of the subject matter claimed in this patent application, we are familiar with the patent application and its claims, as well as the development of the claimed invention. We understand that an Office Action mailed March 30, 2009, rejects claims 1, 8, 9-13, 15, 16, and 19 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,320,701 of Haut et al. ("the Haut patent"), and furthermore, rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. §103(a) as being obvious over the Haut patent.

2. We understand that the Haut patent has a §102(e) date of June 2, 2003 (based on its filing date). We believe that the facts set forth below evidence that the invention claimed in this patent application was at least conceived prior to June 2, 2003, which is the earliest priority date that could possibly be claimed by the Haut patent.

3. Before June 2, 2003, at least two pages of drawings of the claimed invention were prepared, a redacted copy of which is attached hereto as Exhibit A. These drawings, which are dated (redacted) prior to June 2, 2003, illustrate the details of the invention as claimed in the independent claims, thus showing conception of the invention. In particular, the drawings illustrate a suture anchor for anchoring tissue to bone that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in a suture channel of the anchor. An elongate body defined by a longitudinal axis of symmetry and having a first, leading end and a second, trailing end is illustrated at least in Figures A, Sections A-A, and the perspective views of pages 1 and 2, and Figure B of page 2. Two opposed surfaces between the first and second ends and a plurality of sidewalls extending between the two opposed surfaces is illustrated at least in the Figures A and the perspective views of pages 1 and 2. Figures A and the perspective views of pages 1 and 2 also illustrate a flared portion formed on the second end and extending from one of the sidewalls. The flared portion is adapted to engage and anchor into bone tissue. A suture channel formed in the elongate body for passage of a suture strand therethrough and extending between the two opposed surfaces is illustrated at least in Section A-A of page 1 and Section A-A and Figure B of page 2. As shown, the suture channel is oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and as shown in Figures A of pages 1 and 2, a centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion.

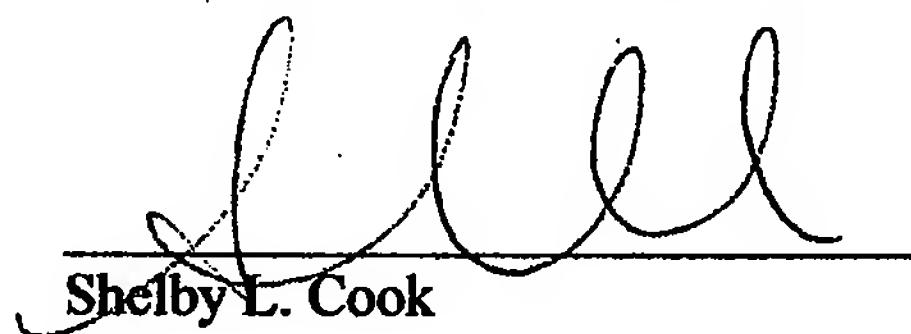
4. We were reasonably diligent in constructively reducing our invention to practice by filing a patent application on June 27, 2003, which is less than one month after the earliest priority date that could possibly be claimed by the Haut patent.

5. All of these acts relating to the conception and completion of this invention took place in the United States.

6. We further declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 14 Aug - 2009



Shelby L. Cook

Date: \_\_\_\_\_

Jose E. Lizardi

Date: \_\_\_\_\_

Karl S. Reese

Date: \_\_\_\_\_

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: \_\_\_\_\_

Shelby L. Cook



\_\_\_\_\_  
Jose E. Lizardi

Date: \_\_\_\_\_

\_\_\_\_\_  
Karl S. Reese

Date: \_\_\_\_\_

\_\_\_\_\_  
Thomas A. Shepard

1845139.1

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Date: \_\_\_\_\_

Shelby L. Cook

Date: \_\_\_\_\_

Jose E. Lizardi

Date: 08/25/09

Karl S. Reese  
Karl S. Reese

Date: \_\_\_\_\_

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: \_\_\_\_\_

Shelby L. Cook

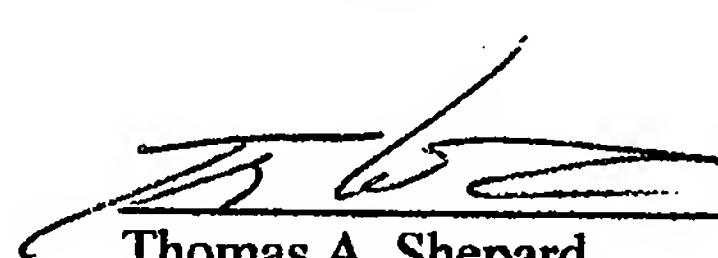
Date: \_\_\_\_\_

Jose E. Lizardi

Date: \_\_\_\_\_

Karl S. Reese

Date: 8/19/09



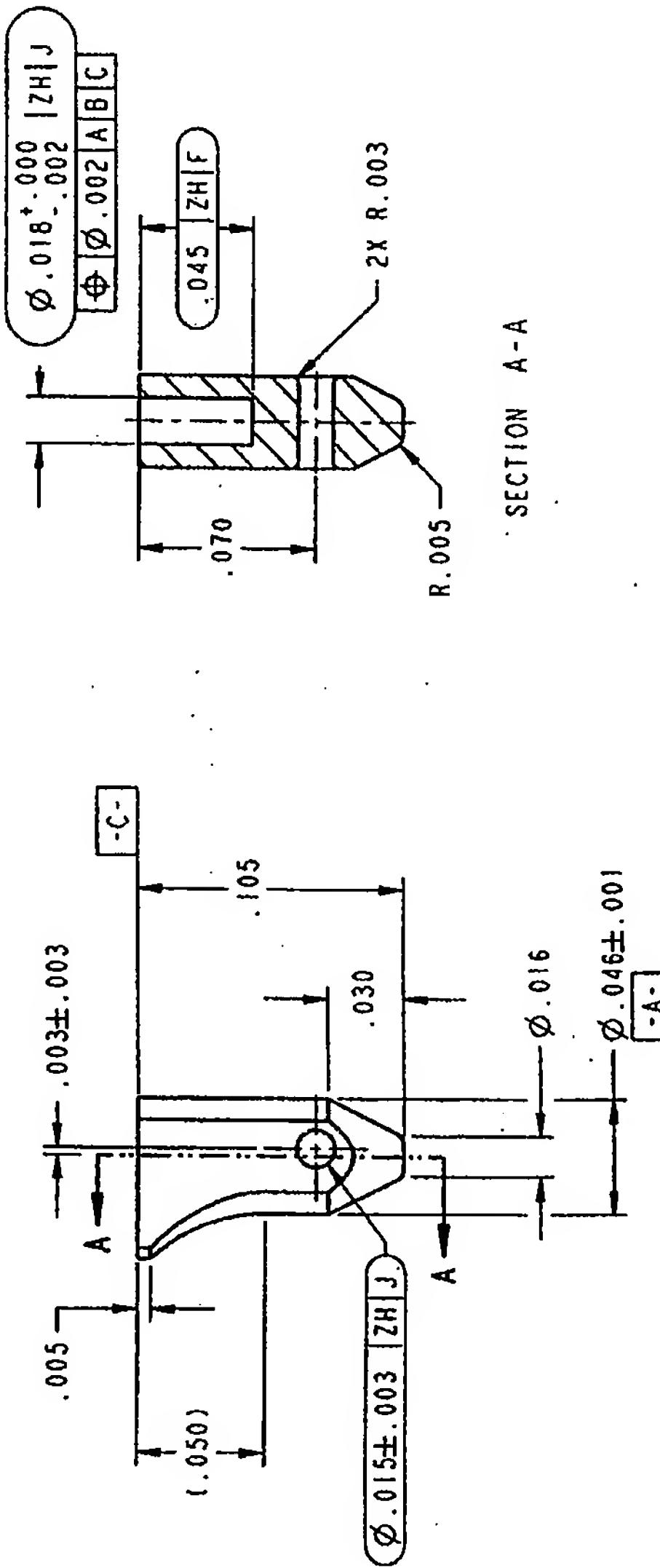
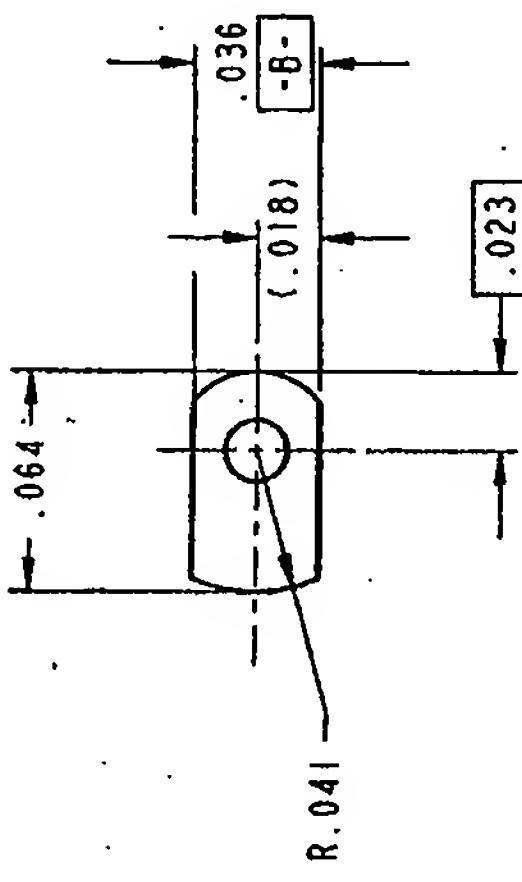
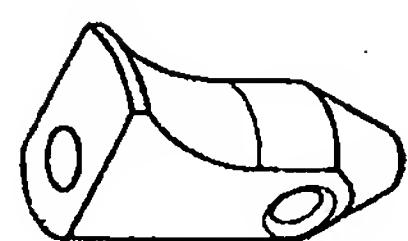
Thomas A. Shepard

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## **Exhibit A**

DO NOT SCALE THIS DRAWING

REVISION					
REV.	DESCRIPTION	R&D DATE	MFG DATE	APPR DATE	APPR DATE
1	DRAWING NUMBER WAS M000010 REV 01	DB	LB		
2	DELETED NOTE 10 AND 11 MATERIAL WAS RFW	LB			
3	ADDED GEM TOL. UPDATED NOTE 1 NOTE 7 & 8 DMB	PMD			
4	.005 WAS .010, NOTE 9 .005 WAS .004 .064 WAS .061, R.041 WAS R.038. .05 WAS .130, .030 WAS .055. .005 WAS R.005, CORRECTED POSITION TOLERANCE	SC	LB		



SECTION A-A

NOTES:

- MATERIAL: REFERENCE TO P/N 105339 FOR MATERIAL SPECIFICATIONS  
DYE PART #06297, DIC BLUE #6, RATIO PLA: DYE, 10,000:1  
CERTIFICATION REQUIRED
- FINISH: SPE/SPI #2 (REF).
- PARTING LINE .006 MAX MISMATCH ALLOWABLE IN Y AXIS.  
IN X AXIS, .003 MAX MISMATCH ALLOWABLE IN Y AXIS.
- PART TO BE FREE OF TOOL MARKS, SINKS, DIRT,  
FOREIGN MATTER AND HOLD RELEASE.
- MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT. USE  
VIRGIN MATERIAL ONLY (NO REGRIND ALLOWABLE). APPLIES  
ONLY TO OUTSIDE SUPPLIERS.
- PARTS TO BE PACKAGED CLEAN, IN POLY BAGS.
- .005 MAX GATE VESTIGE.
- .005 MAX ALLOWABLE FLASH.
- EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.
- INSPECT TO THE REQUIREMENTS OF SOP 201085.  
GENERAL INCOMING INSPECTION PROCEDURE.
- SEE NOTES

ITEM NO.	PART OR IDENT. NO.	DESCRIPTION	RECD.
1	S. DASILVA Part No. 212857	ANCHOR, ABSORBABLE.	06/15/2007
2	H. CAUDWELL Part No. 212856	ANCHOR, MICRO (PLA)	06/15/2007
3	D. BELLOU Part No. 212855	THIRD ANGLE PROJECTION	06/15/2007
4	C 106947	SEE NOTES	06/15/2007

PRINTED DATE: 2011 PRINT 1

ITEM NO. C 106947

SEE NOTES

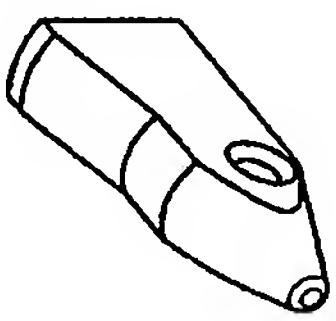
PRINTED DATE: 2011 PRINT 1

ITEM NO. C 106947

SEE NOTES

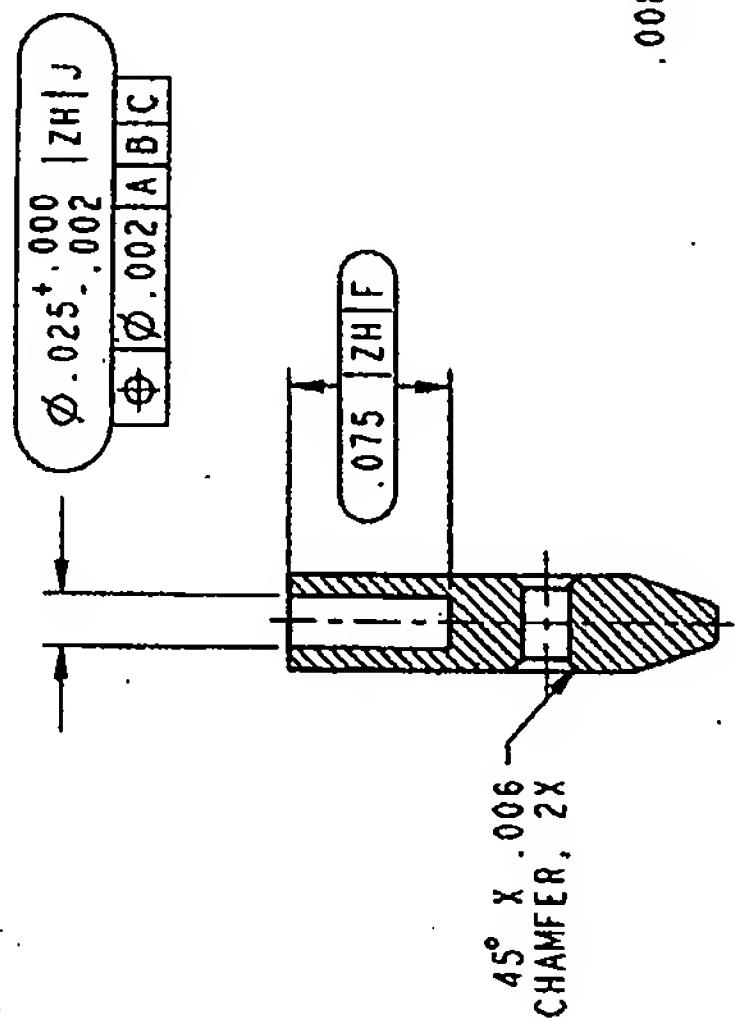
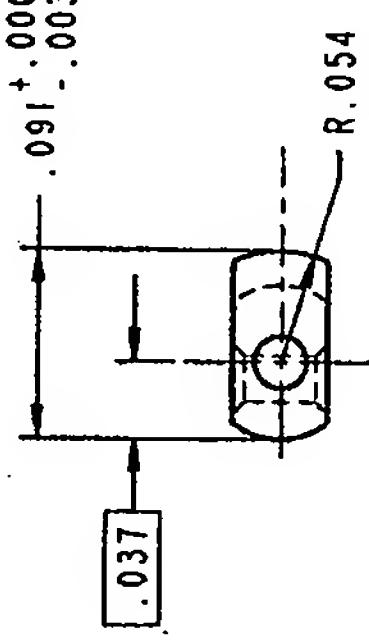
PRINTED DATE: 2011 PRINT 1

DO NOT SCALE THIS DRAWING

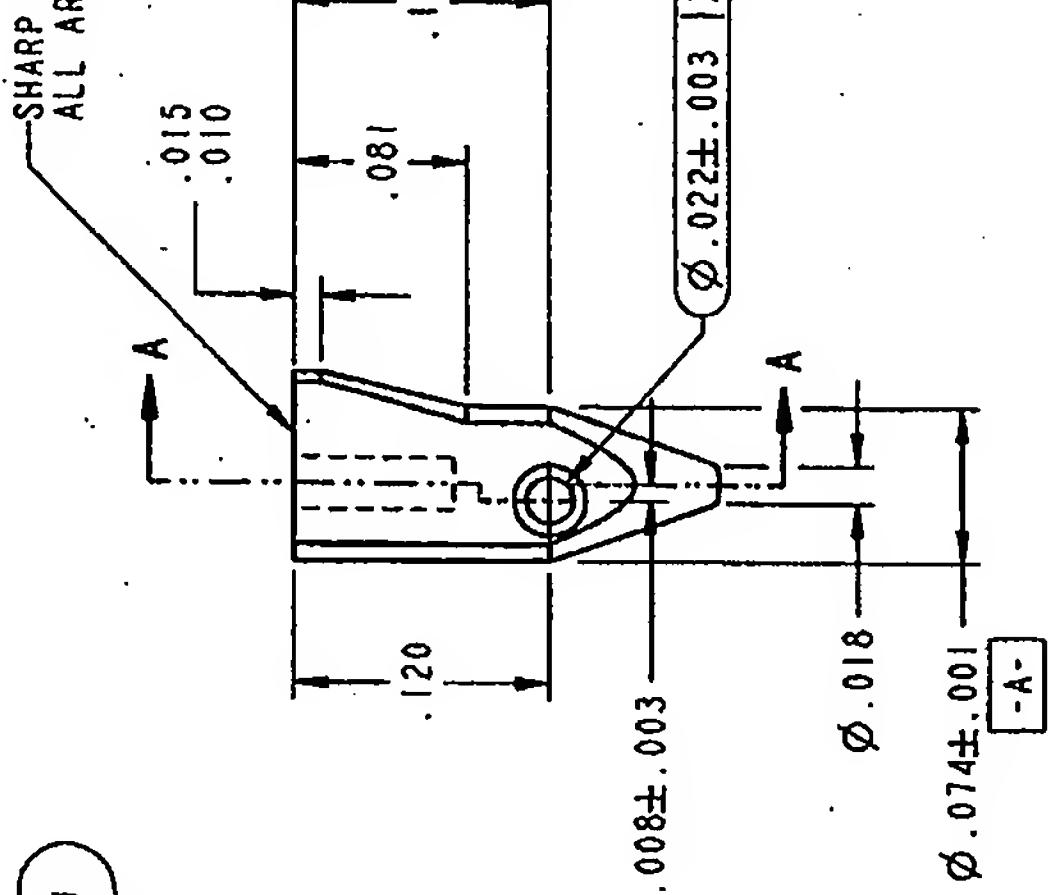


REVISION					
REV	DESCRIPTION	R&D APPROV	MFG APPROV	DATE	DATE
3	ADDED .005 TOL. UPATED NOTE 1. NOTE 7 & 8 .005 WAS .010. NO NOTE 9. .001 WAS .004	DMB	PMD		
4	.007 + .005 - .000 WAS .002. REMOVED .008 FLAT. ADDED SHARP EDGE NOTE 45° X .006 CHAMFER. 2X R.006	DMB	PMD		
5	ADDED .015-.010 STEP DIMENSION ADDED R.077 REF. DIMENSION CORRECTED POSITION TOLERANCE	SC	LB		
6	.037 WAS .033. .081 WAS .087 .014 WAS .016. .081 WAS .085	SC	LB		
7	.008 ± .003 WAS .005 ± .003. .120 WAS .110	SC	PMD		

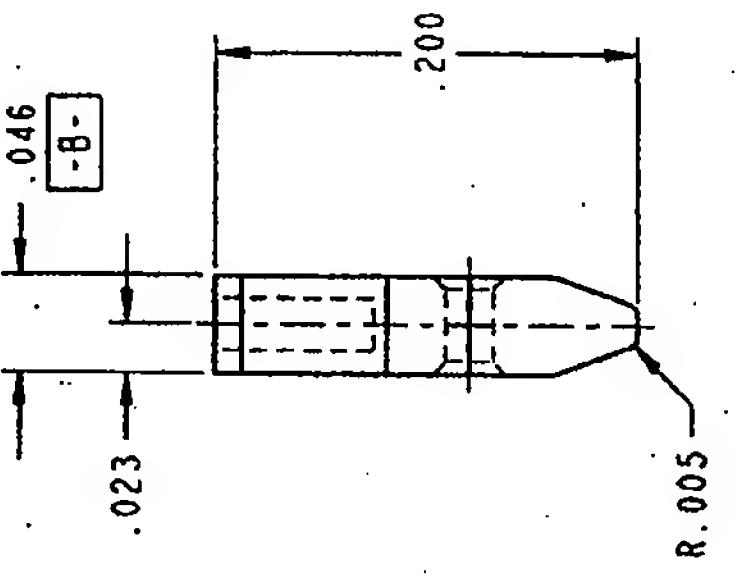
0556901



SECTION A-A



SHARP EDGE REQUIRED  
ALL AROUND



R.005

NOTES:

1. MATERIAL: REFERENCE TO P/N 105339 FOR MATERIAL SPECIFICATIONS
2. FINISH: SPE/SPI #2 (REF).
3. PARTING LINE .006 MAX MISMATCH ALLOWABLE  
IN X AXIS. .003 MAX MISMATCH ALLOWABLE IN Y AXIS.
4. PART TO BE FREE OF TOOL MARKS, SINKS, DIRT,  
FOREIGN MATTER AND MOLD RELEASE.
5. MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT. USE  
VIRGIN MATERIAL ONLY (NO REGIND ALLOWABLE). APPLIES  
ONLY TO OUTSIDE SUPPLIERS.
6. PARTS TO BE PACKAGED CLEAN. IN POLY BAGS.
7. .005 MAX GATE VESTIGE.
8. .005 MAX ALLOWABLE FLASH.
9. EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.

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9. EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.

ITEM NO.	PART OR IDENT. NO.	DESCRIPTION
1	S. DASILVA part CERTIFIED N. CAUDWELL part IMPROVE D. BELLOU part NOTICE	ANCHOR, ABSORBABLE. MINI (PLA)
2	212850	MADE WORKFLOW OF TOP ACTIVATION, MAINTAIN STABILITY, AND STRENGTH THROUGHOUT THE PROCESS.
3	212851	MADE WORKFLOW OF TOP ACTIVATION, MAINTAIN STABILITY, AND STRENGTH THROUGHOUT THE PROCESS.
4	212852	MADE WORKFLOW OF TOP ACTIVATION, MAINTAIN STABILITY, AND STRENGTH THROUGHOUT THE PROCESS.
5	C	NEXT ASSY CATALOG NO. APPLICTION
6	SEE NOTES	SEE NOTES
7	SEE NOTES	SEE NOTES

match

0556901

106950

7

1. 1 part  
2. 1 part  
3. 1 part  
4. 1 part  
5. 1 part  
6. 1 part  
7. 1 part  
8. 1 part  
9. 1 part  
10. 1 part